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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/051,827 05/01/98 ZIMMERMANN

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EXAMINER

BERCH, M

ART UNIT

PAPER NUMBER

1624

10

DATE MAILED:

09/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/051,827

Applicant(s)

Zimmermann

Examiner
Mark L. Berch

Group Art Unit
1624



☒ Responsive to communication(s) filed on Aug 7, 2000.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 2-4, 6, and 14-19 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 15 is/are allowed.

☒ Claim(s) 2-4, 6, 14, and 16-19 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 6, 14, 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for most choices, does not reasonably provide enablement for substituted carbocyclic rings and substituted heterocycles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The reasons were given previously. Cancellation of claim 1 removed the problem of improper dependence. However, as stated previously, such choices do not fall within the ambit of Formula I and hence have no ascribed utility, since the utility is tied to formula I. Thus for example, the choice which bridges lines 7-8 of page 4 is a substituted carbocycle. However, Formula I permits substituents on the "aliphatic hydrocarbon radical" (page 1, last line) but not on the carbocyclic and heterocyclic

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choices (see next line). Hence, such substituted carbocyclic and heterocyclic rings are not enabled in terms of how to use.

Claims 2, 3, 14, 16, 18-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The replacement of thio with mercapto constitutes new matter. There is no reason why one of ordinary skill in the art reading this specification would know that mercapto rather than thioxo (=S) was intended.

Claims 2, 16, 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The scope of claim 19 is unclear. This does not set forth a well defined category of tumors, and thus one of ordinary skill in the art is forced to unduly experiment to determine its scope. Determining the ability of compounds to inhibit the growth of tumors is a difficult and painstaking task. Suppose that a given Inhibitor X when administered to a patient with Tumor D does not obtain a response. Does one then conclude that Tumor D does not fall within this claim? Keep in mind that:

A. It may be that the next patient will respond. It is quite common for pharmaceuticals to work only with some people, not all. Thus, how many need to be tested?

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would that qualify? Keep in mind that such a "response" would normally be considered as a failure, i.e. that the compound isn't effective.

As a result, determining the true scope of the claim will involve extensive and potentially open-ended research. Without it, one skilled in the art cannot determine the actual scope of the claim. Hence, the claim is indefinite.

A claim to the inhibition of the kinase is suggested and would be acceptable.

2. Claim 16, fourth from last line of claim , should be "1,4", not ",4" in the last full term on that line.

3. Claim 2 is not in proper form; it has both deletion brackets and brackets to be printed in the same claim and the printer cannot tell these apart. For example, the same line which has "[thio]" on page 3 also has brackets which are to be printed. See MPEP 714.22.

Claim Rejections - 35 USC § 102 and 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2, 6, 14, 18, 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Mackman.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mackman.

The reasons were given previously. These claims have rejections under 35 USC 112, paragraph 1 and hence are not enabled as of their priority dates for the same

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reason. This is the sole problem, so that when the paragraph 1 rejections are taken care of, this rejection will disappear as well.

The examiner notes for the record that R₅ no longer can be hydroxyalkyl and hence there is no conflict with the claims of Mackman.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718.

Mark L. Berch

Primary Examiner

A handwritten signature in black ink, appearing to read 'Mark L. Berch', is written over the printed name and title.

Group 1620 - Art Unit 1624

September 8, 2000



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